Supreme Court, U.S.
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No. 99-1517

IN THE

Supreme Court of the United States

UNIVERSAL MANAGEMENT SERVICES, INC., NATURAL CHOICE, INC., PAUL M. MONEA and PAUL A. MONEA,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

REPLY BRIEF

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STATEMENT PURSUANT TO RULE 29.6

Petitioners, Universal Management Services and Natural Choice, have no parent corporations and no publicly held company owns 10% of the stock of either Petitioner.

ARGUMENT

1. Restitution Is Not an Available Remedy Under the FDCA and the Courts Below Are In Disagreement Regarding Whether Remedies Other Than Injunctive Relief, Seizure, or Criminal Prosecution Are Permissible

In the Brief for the United States in Opposition to the instant Petition ("Government's Opposition Brief"), the Government argues, rather simplistically, that the district court's power to award restitution automatically flows from its "traditional equitable authority." *See* Government's Opposition Brief at 8. Indeed, the Government's only response to Petitioners' numerous arguments is its assertion that district courts have historically been granted flexibility to fashion remedies. While this contention may be true, it is inapplicable in the instant case because the statutory language of the FDCA *explicitly* lists the remedies Congress has made available to courts. Again, these include: (1) injunctive relief, 21 U.S.C. § 332; (2) criminal prosecution, 21 U.S.C. § 333; and (3) seizure, 21 U.S.C. § 334. Notably, the FDCA does not list the familiar catch-all "appropriate equitable relief" unlike the statutes at issue in the cases cited by the Government. *Compare Mertens v. Hewitt Assocs.*, 508 U.S. 248, 255 (1993) (29 U.S.C. § 1132(a)(3) permits retirement plan participants to bring civil actions to obtain "appropriate equitable relief") (emphasis added); *Tull v. United States*, 481 U.S. 412, 424 (1987) (33 U.S.C. § 1319(b) allows the Administrator to commence a civil action for "appropriate relief," including a permanent or temporary injunction) (emphasis added). The Government may not wave the "talisman of equity" to justify the creation of new rights and remedies when faced with a clearly defined statutory scheme that does not expressly permit "other equitable relief." The

FDCA is a statute which "by necessary and inescapable inference" restricts the district court's equitable jurisdiction. *Mitchell v. Robert DeMario Jewelry, Inc.*, 361 U.S. 288, 291 (1960) (quoting *Porter v. Warner Holding Co.*, 328 U.S. 395, 397-98 (1946)). Congress was well aware of the existence of restitution as a potential remedy when it enacted the FDCA. In fact, it provided for restitution as a remedy for cleanup of clandestine methamphetamine sites. *See* 21 U.S.C. § 853. The absence of such a remedy elsewhere in the statute evidences Congress' intent *not* to grant it to district courts under any other circumstances.

In response to Petitioners' argument that the district court's expansion of the FDA's power is in clear conflict with several other district court decisions, including *United States v. Ten Cartons, Ener-B Nasal Gel*, 888 F. Supp. 381 (E.D.N.Y.), *aff'd*, 72 F.3d 285 (2d Cir. 1995), *United States v. Superpharm Corp.*, 530 F. Supp. 408 (E.D.N.Y. 1981), and *United States v. C.E.B. Products, Inc.*, 380 F. Supp. 664 (N.D. Ill. 1974), all of which *restricted* the FDA's remedies to those expressly enunciated in the FDCA, the Government merely states that these cases "were wrongly decided." Government's Opposition Brief at 11. We submit that, in fact, these cases were correctly decided and are consistent with congressional intent to create a comprehensive scheme of enforcement under the FDCA, in regard to which restitution is neither available nor necessary.

Whether or not these cases were correctly decided, however, this type of inconsistency among lower federal courts is precisely the type of situation this Court should address and clarify. *See Ivan Allen Co. v. United States*, 422 U.S. 617, 623-24 (1975) (certiorari granted on claimed "conflict in principle" with a district court opinion that had been summarily affirmed by court of appeals).

2. Holding Monea Jr. Liable Constitutes an Improper Extension of the *Dotterweich* Standards For Individual Liability Under the FDCA, In Violation Of Due Process

In *United States v. Park*, 421 U.S. 658, 673-74 (1975), this Court refined its decision in *United States v. Dotterweich*, 320 U.S. 277 (1943), to conclude that only a defendant who failed to act on authority to prevent or correct the violation should be held individually liable under the FDCA. *See Park*, 421 U.S. at 673-74. A finding of individual liability is only appropriate when the evidence demonstrates that the defendant had, by reason of his position in the corporation, *responsibility and authority* either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so. *See id.* at 673-74 (emphasis added). Recognizing the clear language of this Court and the obvious shortcomings of its argument before the Sixth Circuit, the Government now contends, for the first time in five years, that it sought an injunction against Monea Jr., not based on his alleged failure to correct a violation of the statute by virtue of his status and authority, but rather based on his own direct conduct and intent. *See* Government's Opposition Brief at 14. We submit that it is simply too late for Respondent to assert new theories of liability. Nor does the evidence in the record support the *new* allegation that Monea Jr. directly violated the FDCA. Monea Jr. is alleged to have been in charge of shipping, inventory, and customer service. This hardly supports the contention that he purposely allowed misbranded products to be shipped in interstate commerce.

The cases cited by Petitioner demonstrate that the *Park* standards have been employed only to hold liable those individuals who were *both* officers or owners of the companies in question *and* who possessed real power to correct the violation. *See United States v. Torigian Labs.*, 577 F. Supp. 1514, 1529-30 (E.D.N.Y. 1984); *United States v. New England Grocers Supply Co.*, 488 F. Supp. 230, 234 (D. Mass. 1980); *United States v. Starr*, 535 F.2d 512, 515-16 (9th Cir. 1976). The record in this case fails to reveal any evidence supporting the notion that Monea Jr. had the power or authority to prevent or correct the violation. Whether or not he may have "maintained various forms of independent authority and responsibility," *see* Government's Opposition Brief at 13, is irrelevant to the application of *Park*. The holding below dangerously expands liability under *Park* to place virtually any manager or employee with some degree of authority at risk for company violations that occurred on their watch and skates perilously close to a strict liability standard which, we submit, is contrary to *Park*, and violative of due process.

CONCLUSION

The Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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